Special Commission on
Ambulatory Surgical Centers & Medical Diagnostic Services

June 30, 2007

Clerk of the Senate
Clerk of the House of Representatives

The Special Commission on Ambulatory Surgical Centers & Medical Diagnostic Services hereby submits its report. The Commission, established by Section 105 of Chapter 139 of the Acts of 2006 (the FY07 Budget), first met on September 27th and held several subsequent meetings, informational sessions and a public hearing. Pursuant to Section 105, the Commission is required to submit this report, along with recommendations for legislation, by July 1, 2007.

Early on it the process of examining the issues before them, Special Commission members identified a number of areas of concern within the relatively broad language in the legislative mandate. Chief among these concerns were issues of access, cost, quality, and safety, and commission meetings included several lively discussions concerning the potential impact on these area—and particularly on patients—of changes in the current system of regulating Ambulatory Surgical Centers (ASCs) and Medical Diagnostic Services. The Legislature's directive to the Commission was essentially two-fold—to study both ASCs and medical diagnostic services. Commission members recognized that, although both topics raised some similar concerns about access, cost, and quality, each of the two involved rather different operational and regulatory issues. As a result, the Commission generally treated the two topics separately, an approach that is reflected in this report.

The Commission's report is based on information gathered at two education sessions held for Commission members, as well as testimony (both invited and voluntary) presented at a public hearing and additional research done by staff and interns of the Health Care Financing Committee. Treatment of this information is organized in the form of separate discussions of a number of questions that were identified by the Commission in each of the two relevant areas (ASCs and medical diagnostic technology). This set of discussions forms the main body of the report and is followed by a series of recommendations. At this time, the Commission does not recommend specific legislation; rather the

recommendations in this report lay out principles and direction for future legislation and possible regulatory changes.

The final meeting of the Commission took place on June 12, 2007, at which time members discussed further revisions to the recommendations. There was a clear consensus of approval for the report, although individual members expressed various reservations about certain aspects of the recommendations. Thus, it should be noted that endorsement of the report is not intended to signify a particular member's or organization's acceptance of all of the recommendations contained in it. The Commission members recognize the complexity of the issues under consideration, as well as the strong feelings on various sides of those issues, and Commission members were invited to send letters with further comments that are included in Appendix D.

We hope that the work of the Commission and submission of this report will be another step in ensuring a high quality health care delivery system that serves the needs of all the residents of Massachusetts.

Sen. Richard T. Moore, Co-Chair

Rep. Patricia A. Walrath, Co-Chair

(See next page for additional signatures)

Executive Office of Health & Human Services

Massachusetts Association of Ambulatory Surgical Centers

Department of Public Health

Fallon Clinic

Office of Medicaid

Harvard Vanguard Medical Associates

Massachusetts Hospital Association

Massachusetts Association of Health Plans

Massachusetts Council of Community Hospitals

Blue Cross Blue Shield of Massachusetts

Massachusetts Medical Society

Health Care Economist (Senate)

Massachusetts Radiological Society

Health Care Economist (House)

Report of the Special Commission on

Ambulatory Surgical Centers & Medical Diagnostic Services

July 1, 2007

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   - Carol A. Straney, Area Center manager, MRI of Dedham
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I. STATUTORY MANDATE

The Special Commission on Ambulatory Surgical Centers & Medical Diagnostic Services was established by Section 105 of Chapter 139 of the Acts of 2006 (the FY2007 budget). The authorizing language follows.

SECTION 105. Notwithstanding any general or special laws to the contrary, there shall be a special commission to make an investigation and study of the impact of 1) single- and multi-specialty ambulatory surgical centers and 2) medical diagnostic or therapeutic services rendered in conjunction with innovative services and new technology as defined by the department of public health, on the health care delivery system, cost of health insurance, Medicaid costs, and uncompensated care, provided that the study shall consider a range of such facilities and services, including hospital-owned, physician-owned, and investor-owned. The study shall include a cost-benefit analysis, and shall also examine the effect of such facilities on access to health services, and the impact on the provision of hospital-based services.

The commission shall consist of 16 members, 1 of whom shall be the secretary of health and human services or his designee, 1 of whom shall be the commissioner of the department of public health or his designee, 1 of whom shall be the director of the office of Medicaid or his designee, 1 of whom shall be the senate chair of the joint committee on health care financing, 1 of whom shall be the house chair of the joint committee on health care financing, 1 representative from the Massachusetts Hospital Association, 1 representative from the Massachusetts Association (sic) of Community Hospitals, 1 representative from the Massachusetts Medical Society, 1 representative from the Massachusetts Radiological Society, 1 representative of the Massachusetts Association of Ambulatory Surgical Centers, 1 of whom shall represent Fallon Clinic, 1 of whom shall represent Harvard Vanguard Medical Associates, 1 representative from the Massachusetts Association of Health Plans, 1 representative from Blue Cross Blue Shield of Massachusetts, a health care economist appointed by the speaker of the house of

representatives and a health care economist appointed by the president of the senate. The commission shall be co-chaired by the senate and house chairpersons of the joint committee on health care financing.

The commission shall meet no later than October 1, 2006, and file a report, with recommended legislation, with the clerks of the senate and the house of representatives no later than July 1, 2007 .

II. MEMBERSHIP

Senate Chair	Senator Richard T. Moore
House Chair	Representative Patricia A. Walrath
Executive Office of Health and Human Services	Paul Dreyer, Director of Health Quality
Department of Public Health	Ed Kiely, Chief of Staff
Office of Medicaid	Phyllis Peters, Deputy Assistant Secretary for the Office of Acute and Ambulatory Care
Massachusetts Hospital Association	Timothy F. Gens, Senior Vice President, Policy and Regulation General Counsel
Massachusetts Council of Community Hospitals	Linda Shyavitz, President & CEO, Sturdy Memorial Hospital
Massachusetts Medical Society	Dr. Thomas Hutchinson
Massachusetts Radiological Society	Dr. John Dubrow
Massachusetts Association of Ambulatory Surgical Centers	Dr. Jerry M. Schreibstein
Fallon Clinic	Dr. Stephen Pezzella, President & CEO
Harvard Vanguard Medical Associates	Gene Wallace, Executive Vice President & CEO
Massachusetts Association of Health Plans	Dr. Marylou Buyse, Executive Director
Blue Cross Blue Shield of Massachusetts	Steven Fox, Senior Director of Provider Relations (replaced Sarah Iselin)
Health Care Economist (Senate)	Dr. Jean Mitchell, Professor of Public Policy, Georgetown Public Policy Institute, Georgetown University
Health Care Economist (House)	Dr. Haiden Huskamp, Associate Professor of Health Economics, Harvard Medical School

III. COMMISSION PROCESS

The Special Commission held a variety of meetings during which members attempted to further define and clarify, within the broad scope of the legislative mandate, specific and pertinent issues that could reasonably be addressed by the Commission in the time allowed for its work. These sessions were followed by a public hearing at which testimony (including solicited testimony on questions and issues that had been identified in previous meetings) was heard. The Commission then met on June 12th to discuss a final set of recommendations.

The following is a list of Commission meetings (all held at the State House).

September 27, 2006 **Organization meeting**
Introduction of Commission members and preliminary identification of issues.

October 23, 2006 **Educational Session**
Stark Law presentations by panel consisting of:

- Thomas Crane, Health Law Attorney, Mintz Levin
- David Levin, Professor and Chairman Emeritus of the Department of Radiology, Jefferson Medical College and Thomas Jefferson University Hospital
- Wes Cleveland, Health Law Legal Counsel, Departments of Private Sector Advocacy and State Legislation, American Medical Association
- Colin Zick, Health Law Attorney, Foley Hoag
- Dr. Thomas Parker, Bay State Medical Center

November 28, 2006 **Educational Session**
Determination of Need (DoN) Briefing by Paul Dreyer (Special Commission member; Director, Bureau of Quality Assurance and Control, Massachusetts Department of Public Health).

January 16, 2007 **Meeting**
Discussion of next steps, preliminary identification of pertinent issues and questions. Following this meeting legislative staff compiled a list of questions raised, which was circulated by e-mail for further additions and comment.

February 13, 2007 **Meeting**

Further discussion of pertinent issues and questions; plan for hearing and solicitation of expert witnesses.

March 21, 2007 **Public Hearing**

Invited Testimony:

- Tom Crane, Health Care Attorney, Mintz Levin
- Jean Mitchell, Professor of Public Policy, Georgetown Public Policy Institute
- John Blair, Chief of Staff, Connecticut Office of Health Care Access
- Joan Gorga, Director of DoN Program, Massachusetts Department of Public Health
- Gail Palmeri, Director of Hospital Licensing Program, Massachusetts Department of Publich Health
- Dr. David Shapiro, physician/ASC community

For a list of all people testifying, see Appendix C

June 12, 2007 **Final Meeting**

Discussion of final recommendations.

IV. BACKGROUND

Introduction

The Special Commission was created in 2006 in response to growing concerns about two separate, but related, topics: 1) ambulatory surgical centers and 2) medical diagnostic technology, specifically Magnetic Resonance Imaging (MRI) services.[1] While the two topics raise some similar questions about quality, access to health services, and cost, several Commission members noted early on that the operational and regulatory issues surrounding each area are actually rather different and Commission discussions tended to focus on each separately. Thus, for purposes of simplification, this report separates discussion of the two types of services. This section provides brief background on each area, and also notes some of the particular concerns that were identified in initial Commission meetings as members sought to further define and clarify the scope of the Commission's work within the fairly broad mandate provided by the Legislature (see Section I above for the statutory language that set up the Commission).

Ambulatory Surgical Centers

Ambulatory Surgical Centers (ASCs) are facilities that perform outpatient surgical procedures that do not require an inpatient overnight hospital stay. ASCs can be (1) freestanding clinics that are licensed by the Massachusetts Department of Public Health (DPH) and go through a Determination of Need (Don) review; (2) owned and operated by a hospital as a separate outpatient department also subject to DoN and Licensure review; (3) operated as a joint venture between a hospital and physician office; or (4) operated as part of a physician office/clinic under what is known as the "physician office exemption" from licensure and DoN review. Despite the different operational categories, the services

[1] Throughout the Commission's proceedings, consideration of medical diagnostic technology focused almost exclusively on MRI issues, and the two terms ("medical diagnostic technology" and "MRIs") are used interchangeably in this report.

provided at the four types of entities are the same; however, Massachusetts law and practice affect the four types of ASCs very differently.

Statutory & Regulatory Background:

One of the most significant areas of state regulation that affects ASCs has to do with the DoN law, which is intended to ensure that there is equitable access to health care services, help maintain standards of quality, and constrain overall health care costs by eliminating duplication of expensive technologies, facilities and services. All hospital-associated ASCs must be operated under a hospital facility license and are subject to DoN review on the same basis as other hospital facilities and services. All clinic-type ASCs are subject to DoN review and require state licensure. Under the DoN law and related regulations someone wishing to open a freestanding ASC and be licensed by DPH must go through the DoN process. In contrast, a DoN review is not required for a physician-owned ASC that relies upon the physician office exemption (the DoN law and related regulation is discussed further in the next section).

ASC Issues:

In its initial meeting and subsequent discussion, Commission members identified a number of issues related to ASCs. These included ASCs' role in providing expanded access to medical services, as well as the possibility that ASCs' operational costs might be lower for private payer, self-insured, or MassHealth patients. At the same time however, concerns were raised about the potential for increased costs to the private and MassHealth market related to duplication of services in a given geographic area, the impact on the current health delivery infrastructure and the ability of hospitals, particularly community hospitals, to maintain their crucial role in that infrastructure, including their emergency departments. Further concerns and questions arose around the issues of quality and safety, including the question of whether current rules and regulations are adequate to ensure safety at ASCs. Questions were also raised concerning the adequacy of current legal and regulatory frameworks to address these concerns. Finally, another relevant issue concerns the use of referrals of patients for ASC services. Physicians who have an ownership stake in freestanding ASCs or in clinics providing

ASC services face a potential conflict-of-interest when referring their patients to use those services. A January 2007 McKinsey Global Institute report found that the reimbursement system creates a strong incentive to self-refer cases—physicians who own equipment and ASCs refer between two and eight times more patients than their peers without equity interest. Because physicians have self-referred many of the less complex procedures out of the hospital setting, hospitals have been left with a highly-acute hospital case-mix, which directly results in increased costs for other services.

Medical Diagnostic Services

The term "medical diagnostic services" refers to the various forms of imaging technology that are used by radiologists in determining a patient's diagnosis. Of principal concern to the Commission were those services that constitute "new technology" or "innovative services" as defined in section 25B of chapter 111 of the Massachusetts General Laws (MGL). Such services include, but are not limited to, magnetic resonance imaging (MRI); computed tomography (CT scan); linear accelerators, lithotripters and positron imaging technology (PET scan). Most imaging services require a large initial capital expenditure for equipment. Services are administered either in freestanding offices that specialize in diagnostic imaging, or in hospitals or group practices that have the equipment on site.

Statutory & Regulatory Background:

State law requires that any provider who wishes to offer a "new technology" must first obtain a DoN from the Department of Public Health (DHP).[2] "New technology" is defined as equipment including but not limited to magnetic resonance imagers, lithotrypters, and linear accelerators, as defined by the department, or a service, as defined by the department, primarily intended for use in the provision of medical or surgical services, whether for diagnostic or treatment purposes, which has received approval from the U.S. Food and Drug Administration or which has been placed in "Approvable Status" by the U.S. Food and Drug Administration, or which has been

[2] MGL 111§25C

authorized for physician use by appropriate professional societies, but which is not in general use for patient care by physicians qualified to operate the equipment or provide the service."[3]

Prior to 1991, practicing physicians were generally exempt from DoN requirements under the physician practice exemption. In 1991 an amendment to the general laws added language (MGL 111, §25C) requiring a DoN review for any provider, physician or other entity that intended to offer MRI services. In 1993 the Legislature expanded the requirement to "the use of innovative services and new technologies." The 1993 amendment grandfathered in equipment acquired before December 31, 1991. It also permitted the filing of a notice of intent (before December 29, 1993) to acquire medical, diagnostic or therapeutic equipment used to provide an innovative service or which is a new technology.[4] Those who filed the notice were issued a Physician Letter of Exemption from the new DoN requirements.

A second area of relevant law has to do with the issue of referrals of patients for MRI services. Physicians who have an ownership stake in medical diagnostic services face a potential conflict of interest when referring their patients to use those services. Self-referral arrangements tend to result in increased utilization of services, some of which may not be medically necessary. This is a significant concern because increased utilization is a major driver of escalating health insurance premiums and rising health care expenditures. To combat this potential problem the federal government enacted the so-called Stark Law,[5] which prohibits Medicare payments for services that result from self-referrals. In addition, 36 states have applied these prohibitions to state, and in some cases private, payers. Massachusetts does not have a set of safeguards similar to the federal rules or these other states.

[3] MGL 111, §25B
[4] See Section 6 of Chapter 350 of the Acts of 1993.
[5] Named after its original sponsor, Pete Stark (D-CA), the "Stark Law" is actually formed by three separate statutes: the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239); the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66); and the Social Security Act Amendments of 1994 (P.L. 103-432).

MRI Issues:

In its initial meeting and subsequent discussions, Commission members identified a number of issues related to MRIs. These included the fate of physician letters of exemption, the potential for over-utilization of services and for abuse in referrals, as well as issues of safety, and access to services (waiting times in some areas, etc).

V. QUESTIONS AND DISCUSSION

Introduction

In two meetings (January 16th and February 13th, 2007) that followed the Commission's initial educational sessions, members sought to further define the scope of the Commission's work and identified a series of questions that needed additional discussion and research before final recommendations could be made. These questions were the focus of the public hearing held on March 21, 2007. Several experts identified by Commission members were invited to testify and asked to address these questions in their presentations; at the same hearing other interested parties also provided testimony that addressed the questions, which had been circulated in advance of the hearing. The remainder of this section contains a discussion of each question that is based on both hearing testimony and additional research by Commission staff. As in the previous section, discussion is divided into two sections, the first dealing with ASC issues, the second with MRI issues.

ASC Questions and Discussion

Questions concerning ASC issues fell into three categories, a) current regulations and experience, b) issues of cost & access, and c) quality issues.

A) Current ASC Regulations and Experience

1) How does the DoN process work in Massachusetts, how does it differ from processes in other states, and should it be changed?

Massachusetts established its Determination of Need (DoN) program in the early 1970s as a means of constraining the growth of health care costs by requiring health care facilities proposing to build new facilities to demonstrate that there was an unmet health care need. Adoption of the DoN process was based on a belief that market forces alone were insufficient to allocate health care resources efficiently, along with a belief that constraining utilization was one way to control costs. Encouragement for development of

DoN processes was offered by federal law (the National Health Planning and Resource Development Act of 1974), which threatened a decrease in federal Medicaid funding to those states that did not implement DoN programs by 1978. However, during the 1980s a new emphasis on market solutions for controlling health care costs led to a repeal of many of the federal provisions related to DoN, and by the late 1990s the DoN process had shifted to a focus on maintaining quality. Today, the Department of Public Health (DPH) describes its mission as the promotion of "availability and accessibility of cost effective quality health care," noting that the program was originally created to "encourage equitable geographic and socioeconomic access to health care services, help maintain standards of quality, and constrain overall health care costs by eliminating duplication of expensive technologies."[6]

The DoN process is governed primarily by MGL 111§ 25C as well as by DPH regulations. Under the statute, a DoN is required in order to make "a substantial capital expenditure for construction of a health care facility or a substantial change in service of any such facility" and compliance with the DoN process is a condition of licensure for these facilities. The term "substantial capital expenditure" is further defined in both statute and regulations; currently a DoN is required for capital expenditures worth more than $13.6 million by acute care facilities and for capital expenditures of more than $1.4 million by clinics. The term "facility" to which the DoN requirements apply is further defined in MGL 111 § 25B and encompasses clinics, including those providing ambulatory surgical services, as defined in MGL 111 § 52. However, that definition of clinic was amended in 1979 to exclude "a medical office building, or one or more practitioners engaged in a solo or group practice...so long as such practice is wholly owned and controlled by one or more of the practitioners so associated or, in the case of a not for profit organization, its only members are one or more of the practitioners so associated."

While this so-called "physician office exemption" was originally intended to protect traditional physician practices from sweeping regulatory changes, it has allowed certain

[6] Mission Statement, Massachusetts Determination of Need Program, Department of Public Health website.

ASCs to operate without going through the DoN process or undergoing associated regulatory oversight by the state, although ASCs that want to receive Medicare reimbursement must meet separate accreditation standards (see additional discussion in question #2 below). Whether they go through the DoN process or operate under the physician office exemption, facilities must go through a DoN process if they wish to add, expand, or develop an innovative service or new technology, such as Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), or others. Finally, ASCs created under a hospital license (i.e., they are a part of the hospital, even if they are physically separate) are not required to go through the DoN process, unless the cost of developing such a service exceeds a certain capital expenditure threshold.

DPH regulations (105 CMR 100.533) set out application and DoN approval processes, and include requirements that facilities make a clear and convincing demonstration that proposed projects are needed and do not duplicate current services, that they demonstrate the reasonableness of proposed expenditures and costs (for instance, the likely effect of the expenditure on public and third-party payer costs can be considered in the DoN approval process), and that they show the primary and preventive health services they will provide, as well as their current contributions to the community. Projects must also meet various criteria designed to prevent duplication of services while providing adequate access. The DoN process requires a public hearing and allows for a public comment period.

Thanks to the federal law and incentives described above, nearly every state created some sort of Certificate of Need (CoN) program during the 1970s. While the relevant federal provisions were repealed in 1987, today about 36 states still have some type of Certificate of Need (CoN) [7] program, although many have made additional changes to the original program. States that do have CoN programs vary rather widely in respect to what services are required to undergo a CoN process—for instance, Oregon's CoN process applies to only two services, while Connecticut and Vermont require a CoN for 28 and 27

[7] "Certificate of Need: State Health Laws and Programs" NCSL website (updated April, 2007). CoN and DoN programs are essentially the same, and the terms are treated synonymously in this report.

different services, respectively (including ASCs). Of the states with a CoN process, 27 include a review of ASCs (including all New England states and New York). There does appear to be an association between the existence of a CoN program and number of ASCs in a state. For instance, when the Pennsylvania CoN statute expired in 1996, the number of ASCs increased by 55%. Likewise, in 2000 there were 44 freestanding ASCs in Missouri before the legislature raised the minimum capital expenditure level subject to CoN review. This relaxation of the CoN law led to a doubling of the number of freestanding ASCs in the state by 2005.[8]

Under the Massachusetts DoN guidelines, DPH stopped accepting applications for multi-specialty ASCs in 1995 and currently runs DoN processes for single-specialty surgery centers only. Since 1992, nineteen DoN applications for ASCs have been reviewed; fourteen were approved, four were denied, and one was withdrawn.

Opinions as to whether the current DoN statute and program in Massachusetts should be changed vary widely. Some Commission members felt that all providers of ambulatory surgical services should be held to the same state standards of licensing, quality and safety review, and DoN requirements without exception. Other Commission members argued that an overly stringent DoN process is stifling the ability of ASCs to provide greater access to ambulatory surgical services, and a lower cost for those services. One member noted that DoN programs were designed before the emergence of current health care trends that involve a shift from in-patient to out-patient care and include the growth of ASCs. At the same time, another member noted that the physician office exemption was also created before the emergence of this trend, suggesting that it was never intended to exclude oversight of office-based ambulatory surgery.

2) What is the state of current regulation and licensure of ASCs (both free standing and those that are part of a physician office) & hospitals and should it be changed?

[8] Written communication, Missouri Certificate of Need Program

As noted above in #1, compliance with the DoN approval process is a condition of licensure by DPH for hospitals and ASCs. However, as is also noted above, current Massachusetts law provides an exemption for certain ASCs under the physician practice exemption.[9] Since the creation of this exemption, multi-specialty practices that are much more advanced and complex than the more conventional physician practices, including ASCs, have emerged and have also been grouped under it, with the result that those ASCs operating under the exemption are not subject to the regulatory oversight that is associated with licensure by DPH.[10] However, in order to receive Medicare reimbursement (without which most ASCs could not survive), an ASC must be certified and must be found to meet the Medicare conditions of participation. The required survey can be conducted by Health Care Quality or by a third-party accrediting agency approved by the Centers for Medicare and Medicaid Services (CMS). Under current law, only if an ASC chooses to be licensed by DPH as a clinic is it required to submit to state licensure requirements and the state healthcare planning process incorporated in the DoN law. Likewise, Medicare certification (or other scrutiny) may be required for private third-party reimbursement. According to DPH, there are currently 55 free-standing ASCs operating in the Commonwealth. Of these, 45 are unlicensed but are Medicare-certified, while ten are both licensed and Medicare-certified. One Commission member claimed that these numbers do not represent all of the ASCs operating in the state, since ASCs that operate under the physician office exemption and choose not to receive Medicare reimbursement would not be included in this count.

Some Commission members argued that Medicare certification is evidence that ASCs meet appropriate quality and safety standards, and pointed out that all physicians practicing in any setting must meet Board of Registration Guidelines. However, other members point out that a 2002 report by the federal Office of the Inspector General found

[9] The impetus behind this exemption was to prevent services and equipment that were typically associated with traditional physician practices from being swept up into the regulatory process. While the exemption was intended to apply only to traditional physician group practices, the emergence of more complex and multi-specialty practices, and the growth of entrepreneurial medicine resulted in a need to redefine its scope. In a 1990 opinion issued by DPH's General Counsel, which relied on the Attorney General's 1982 Opinion, the Department determined that a practice under question was not entitled to the exemption.
[10] Such regulatory oversight includes DoN, DPH 1994 DoN Guidelines for Freestanding Ambulatory Surgery Centers, and DPH regulations for the Licensure of Clinics 105 CMR 140.00.

flaws in the Medicare system of oversight, [11] and argue that greater oversight of ASCs is needed, including an accurate count of *all* entities providing ambulatory surgical services in the state is needed.

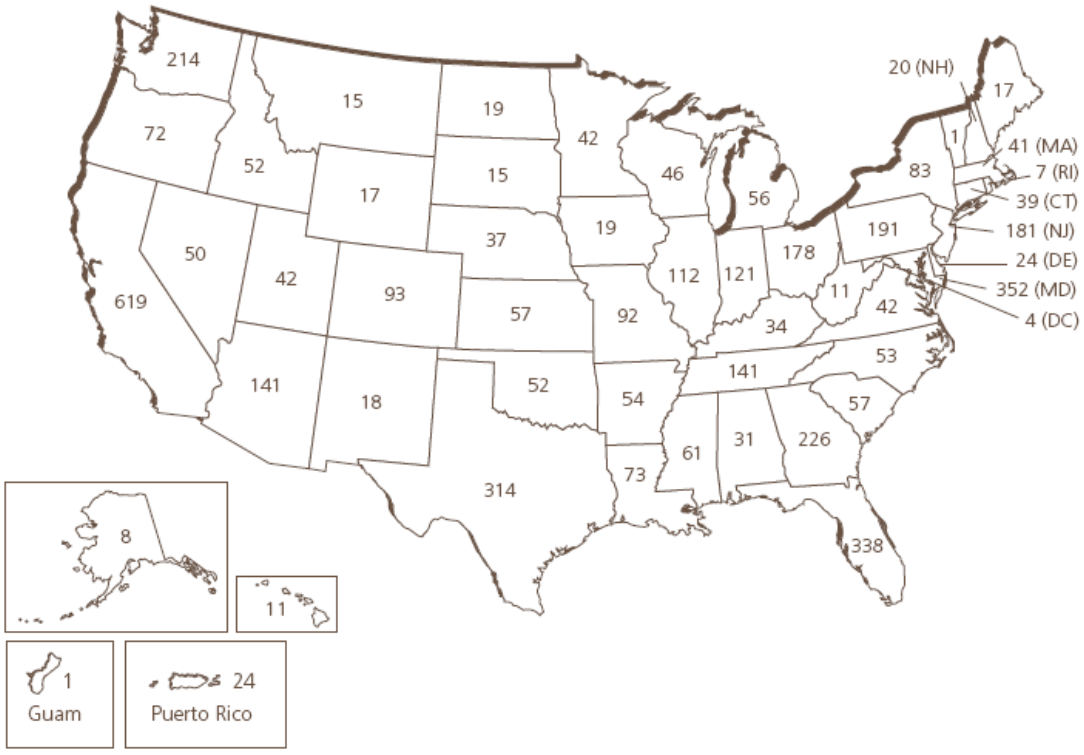
3) What are the numbers and types of ASCs in Massachusetts vs. other states?

As noted above, there are a total of 55 Medicare-certified ASCs in Massachusetts, including 10 ASCs that are also state-licensed; in theory there could be other entities providing surgical services under the physician office exemption that are not Medicare-certified or licensed, and hospital out-patient departments also provide ambulatory surgical services. There are currently about 4,700 Medicare-certified ASCs across the country, with 30% of all ASCs located in California, Texas, and Florida. In contrast to Massachusetts, New Jersey (with a population of 8.7 million) has 192 certified ASCs, while Pennsylvania, with a population roughly double that of Massachusetts, has four times as many certified ASCs (201). Neither of these states has a DoN process for ASCs. By contrast, the state of New York, which does have a DoN process for ASCs, has 83 such facilities (New York's population is slightly more than three times that of Massachusetts). Nationally, ASCs tend to be for-profit entities in contrast to hospitals, which tend to be non-profit (nearly all hospitals in Massachusetts are non-profits, and there is little penetration, thus far, by for-profit ASC chains). Of course, any physician-owned ASC may operate on a for-profit basis; however, the Commission received no authoritative information on the numbers of each type (for-profit vs. non-profit).

The chart below (from FASA, an advocacy organization associated with the Foundation for Ambulatory Surgery) provides a rough picture of the numbers of Medicare-certified ASCs around the country (it is based on older data; hence the discrepancy between the numbers reported on the map and those above).

[11] Janet Rehnquist, Inspector General, *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*, OEI-01-00-00450 (Feb. 2002).

Number of Medicare-certified Ambulatory Surgical Centers by State, 2006



FASA analysis of 2006 Medicare data.

4) **What are current reimbursement methods and how do they differ among ASCs and other types of providers, particularly hospitals?**

The main sources of reimbursement for medical services are commercial insurers, Medicare, and Medicaid. In addition, some individuals pay for their own care (self-payers), while the Uncompensated Care Pool reimburses acute hospitals and Community Health Centers for a portion of the cost of providing care to uninsured residents of Massachusetts. There are differences in the way payers reimburses similar services provided at ASCs and hospitals.

Medicare has separate reimbursement systems for ambulatory surgical procedures performed in a free-standing ASC versus those performed in hospital outpatient departments. Services provided in hospital out-patient departments (HOPDs) are

reimbursed under an Outpatient Prospective Payment System (OPPS) that groups services, based on clinical and cost similarities, into Ambulatory Payment Classifications (APCs). This system is meant to cover the hospital operating and capital costs for the services bundled within each APC, with separate payment for professional services (e.g., physicians' fees).[12]

In contrast, Medicare provides reimbursements for surgical services in free-standing ASCs using individual surgical procedures as the unit of payment. Over 2,000 procedures are grouped into nine payment categories and reimbursed using a fee schedule that ranges from $333 to $1,339 (with adjustments for geographical factors). Physician services are reimbursed separately under a physician fee schedule. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed CMS to implement a revised ASC payment system by January 2008 and this revised system will likely be based on the OPPS groups used to determine hospital payments.[13]

In Massachusetts, Medicaid provides reimbursements to freestanding, multi-specialty ASCs; currently five ASCs are approved by MassHealth (the Massachusetts Medicaid program) for reimbursement. The rates paid are those set by Medicare, and are paid for the facility component of the service only, with separate reimbursements for physicians (similar to Medicare). Medicaid reimburses hospitals for outpatient services using the PAPE (Payment Amount per Episode) methodology developed as part of the annual MassHealth Acute Hospital RFA (request for application). The PAPE system consolidates all out-patient services (surgeries, clinic visits, ancillary services, etc. except laboratory) provided to a single patient in a single day into one PAPE. A case mix factor, which measures the level of services provided at a hospital, is applied to the statewide average rate; these factors are reviewed annually. The PAPE method thus does not reflect the exact costs for services provided during the day; rather it is an average of low and high-cost procedures typically provided by a hospital. Currently average PAPE

[12] MedPAC fact sheet: (http://www.medpac.gov/publications/other_reports/Sept06_MedPAC_Payment_Basics_OPD.pdf)
[13] Med PAC fact sheet: (http://www.medpac.gov/publications/other_reports/Sept06_MedPAC_Payment_Basics_ASC.pdf)

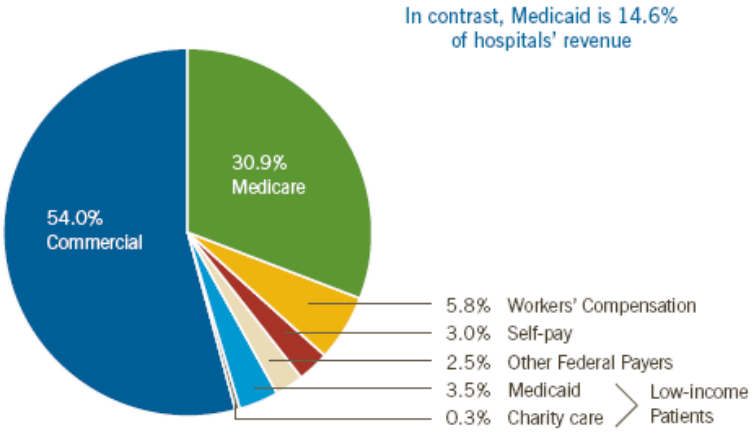
payment range from $124 to $1,500 depending on hospital case mix (with a state average of about $138).

The Commission received very little information concerning the reimbursement practices of private payers. However, in a discussion at one Commission meeting, a member noted that commercial insurance companies structure their reimbursements for hospitals to essentially "lock in" at an aggregate amount they want to pay, and then negotiate how that amount is distributed. In the same conversation, another member noted that there is "tremendous" variation in payments across different types of hospitals, and attributed differences in payments between ASCs and hospitals to an understanding, on the part of payers, that hospitals and ASCs have very different cost structures. One large insurer has described ASCs as a "cost-saving alternative" to traditional hospital care, suggesting that they reimburse ASCs at a lower rate; any such lower rates would, of course, be a consequence of the fact that hospital reimbursements reflect the aggregate costs of providing a full range of hospital care (including costs for unprofitable services).

5) Are there payer mix differences between ASCs and hospitals?

The chart below shows the breakdown of payer types for ASCs nationally, and notes the contrast in regard to the proportion of revenue accounted for by Medicaid reimbursements at hospitals (14.6%) and ASCs (3.5%). Although reliable Massachusetts-specific data for ASCs is not available, due to the lack of state regulation of centers that are not licensed by DPH, given the low number of ASCs that are eligible to receive Medicaid reimbursement in Massachusetts the proportion for ASCs in this state may be different than that shown here.

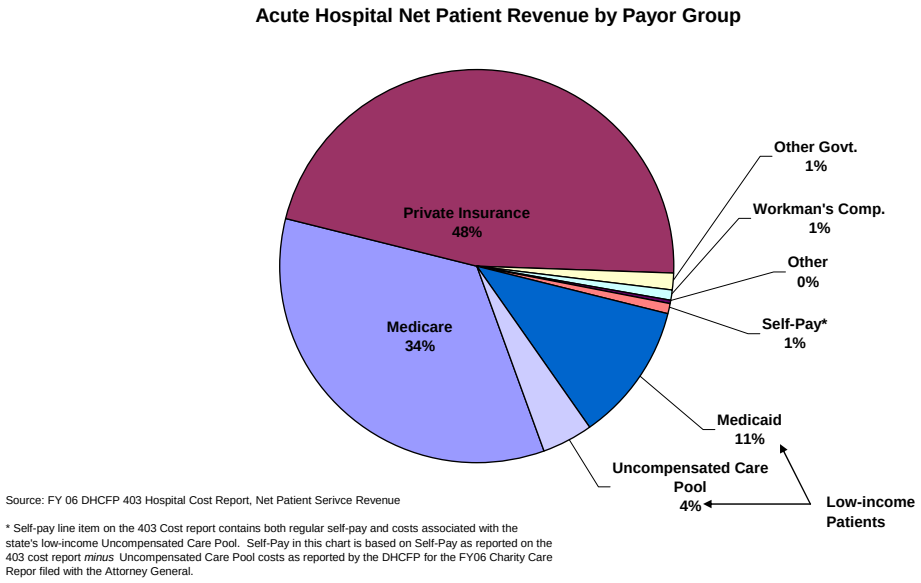
Ambulatory Surgical Center Payer Types Nationally, 2004



Source: Medical Group Management Association (MGMA), *Ambulatory Surgery Center Performance Survey*, 2005 Report, and AHA Annual Survey.

State-level data is available for hospitals, and shows that Medicaid and Uncompensated Care Pool reimbursements account for 15% of the hospital payer mix,[14] although the proportions vary substantially across hospitals and may be lower at community hospitals. The proportion of revenue accounted for by Uncompensated Care Pool reimbursements does not, however, represent the actual level of charity care provided, as these reimbursements cover only a portion of the costs related to providing this form of care. However, it is important to note that hospitals are eligible for reimbursement from the Uncompensated Care Pool for a portion of these costs, while ASCs cannot receive such reimbursement. Note also that the available data likely do not capture unlicensed ASCs operating under the physician practice exemption.

[14] Note that the hospital data include all hospital revenue, not just the portion related to ambulatory surgical services.

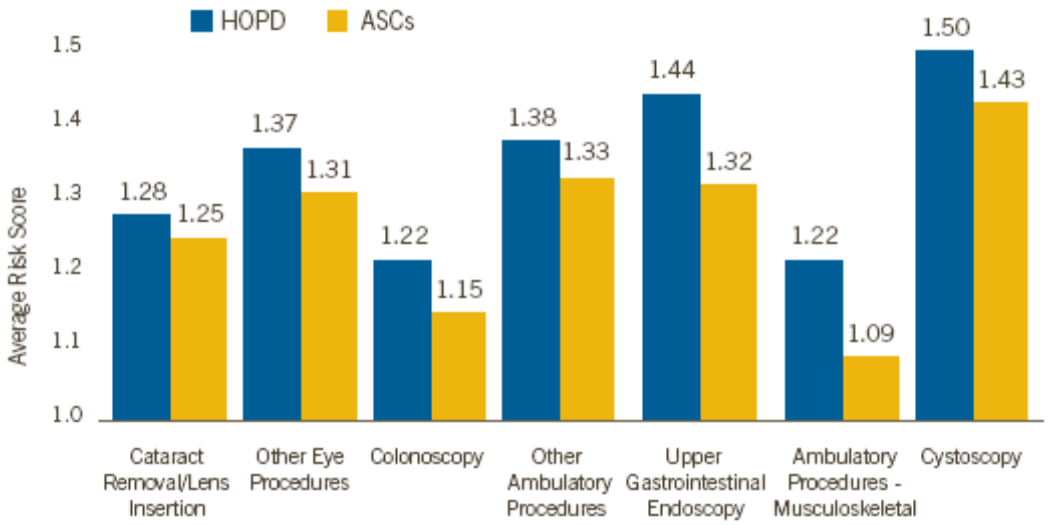


6) Are there case mix differences between ASCs and community hospitals (or other types of hospitals)?

The chart below shows the average patient risk scores (for Medicaid patients in 1999) for services performed in hospital out-patient departments (HOPDs) versus scores for the same services performed in ASCs, and suggests that hospitals are generally treating a higher proportion of patients with potential complications or other health risks. Other studies support this picture. A 2004 Rand Corporation study found that, for cataract and colonoscopy procedures, a larger share of patients treated in HOPDs tended to have hypertension and/or a diabetes diagnosis.[15] Similarly, a 2003 article published in *Health Affairs* found that hospital outpatient surgery departments tend to treat more medically complex Medicare patients than do ASCs.[16] While there are not reliable state-level data to answer this question for Massachusetts specifically, there is no reason to believe that experience should vary in this state.

[15] Wynn, Barbara et al. *Services Provided in Multiple Ambulatory Settings: A Comparison of Selected Procedures* (Rand Health Working Papers), November, 2004, No. 04-3.
[16] Winter, Ariel. *Comparing the Mix of Patients in Various Outpatient Surgery Settings,* Health Affairs 22, no.6 (2003): 68-75.

Average Patient Risk Scores for Medicaid Patients in Ambulatory Surgical Centers (ASCs) vs. Hospital Outpatient Departments (HOPD), 1999



Source: Winter, A, (2003), "Comparing the Mix of Patients in Various Outpatient Surgery Settings," *Health Affairs*, 22: 68-75.

B) Cost & Access Issues

1) How is patient cost-sharing typically structured at ASCs? Are there differences between ASCs (both free standing and physician office based) and hospitals in respects to costs and cost-sharing?

The Commission was able to obtain little information on this topic. A 2004 MedPAC report shows that co-insurance rates for Medicare patients are between 11% and 61% lower (depending on the procedure) at ASCs than at hospitals; however the same report notes that co-insurance rates at hospitals are due to decline over time to a level more similar to ASCs.[17] In fact, given potential changes to Medicare's reimbursement system (see #4 in section A, above), both payments and cost-sharing arrangements at each type of facility could become more similar.

[17] MedPAC March 2004 Report, p.187.

2) Would expanded contracting with ASCs by MassHealth (the state's Medicaid program) affect state Medicaid expenditures (for instance, might savings result?). What are the arguments for and against Medicaid adopting Medicare standards of reimbursement for ASCs?

Note that Medicaid reimbursement practices are discussed above (section A, #4). While makes sense that shifting services to a lower cost setting could lower expenditures for those services, one Commission member noted that higher utilization costs that could occur as a result of physician ownership of (and self-referral to) ASCs might lead to higher reimbursement levels. The Commission received no specific projections of potential savings for the MassHealth program.

3) What would be the impact of expanding ASCs on availability and access to medical services in Massachusetts? In particular, what impact do ASCs and clinics providing ambulatory services pose to the continued viability of (and hence access to) hospital services in Massachusetts?

Discussion of this topic tended to be subjective and based on anecdote. There is little data available to answer this question with any certainty. It might make intuitive sense that expansion of ASCs would allow greater access to the types of medical services they provide, but while such access is certainly desirable, the potential long-term effects of such an expansion are far from clear. MedPAC and CMS have made it clear that there is adequate access to ASCs on a nationwide level; however, this assessment may reflect, in part, the more rapid growth of ASCs in other states and could be less true for Massachusetts.

Hospitals have persistently argued that their services are reflective of the communities in which they operate, and that in order to be responsive to community needs they must offer a wide range of services, some of which are more profitable than others. If an expansion of ASCs means that profitable services are shifted to ASC facilities, it could increase pressure on hospitals to eliminate or restrict services for which they are reimbursed less than the cost of care, and such a shift could ultimately result in reduced access to critical services. At the same time, information provided by DPH indicates that the expansion of ASCs would likely not reduce emergency room crowding, because that

phenomenon results from insufficient staffing of in-patient beds and would not be significantly reduced by the expansion of ASCs.

4) Do ASCs and hospitals provide equal access?

Again there is little hard data to answer this question, although information discussed above indicates that patients at ASCs are less likely to be low-income or high risk. However, any such difference could well be the result of the way the system is currently structured, as well as a need for patients to receive care in a suitable setting. In other words, if ASCs are not eligible for Medicaid or Uncompensated Care Pool reimbursements, it is hardly surprising that they are less likely to see low-income patients. At the same time, it may be desirable for higher risk patients to receive ambulatory surgical services in a hospital out-patient setting where potential complications can be treated more efficiently, and it may likewise be desirable to maintain the viability of hospital infrastructure to provide such care.

C) ASC Quality Issues

1. What are the requirements and current practices concerning safety measures at hospitals and ASCs (both free standing and physician office based)?

Hospitals and different types of ambulatory surgical centers are subject to different sets of standards and regulations concerning the safety.

Hospitals that provide ambulatory surgical services in a hospital-affiliated ASC (or out-patient department) under the hospital's license must adhere to conditions of that licensure. These include allowing the Department of Public Health (DPH) the right to inspect the facility, staff, activities and records with no prior notice, submission of corrections plans if DPH finds deficiencies during inspections, and establishment of a serious complaint procedure. ASCs provide services in facilities specifically designed to perform selected outpatient surgical services. There are essentially three sets of standards that potentially apply to free-standing ASCs: a) Medicare requirements, b) state licensure,

and c) voluntary accreditation.

All ASCs serving Medicare beneficiaries must be certified by the Medicare program. In order to be certified, an ASC must comply with federal safety standards; in addition, federal regulations also limit the scope of surgical procedures reimbursed in ASCs. Generally, services are limited to elective procedures with short anesthesia and operating times not requiring an overnight stay. Under Medicare guidelines, ASCs must maintain complete, comprehensive and accurate medical records, and patients must receive pre- and post-operative examinations to evaluate risks and recovery associated with anesthesia. CMS also requires ASCs to take measures to ensure patients do not acquire infections during their care at these facilities, including active surveillance and prevention techniques. A registered nurse trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever a patient is in the ASC, and ASCs are also required to have an effective means of transferring patients to a hospital for additional care in the event an emergency occurs (in Massachusetts, an ASC must have a written transfer agreement with a local hospital, or all physicians performing surgery in the ASC must have admitting privileges at the designated hospital).

In Massachusetts there are ten free-standing ASCs that are licensed by DPH, in addition to being Medicare-certified, and which are thus subject to further regulation by DPH. This regulation includes a requirement that licensed ASCs grant DPH the right to inspect the facility with no prior notice (similar to hospitals), and a requirement that ASCs are subject to annual State Drug Control registration and periodic on-site surveys and complaint investigations, including requirements for drug storage, preparation and administration, and recordkeeping. At certified-only ASCs, the individual physician must renew State Drug Control registration every 3 years, but there is no consistent oversight of unlicensed ASCs to ensure that they are meeting criteria concerning drug storage, preparation, and administration. Likewise, while DPH-licensed ASCs are required to report to DPH all incidents occurring on their premises that seriously affect the health and safety of patients, ASCs that are only Medicare-certified are not subject to such reporting requirements.

In addition to meeting Medicare certification requirements, many ASCs choose to go through voluntary accreditation by an independent accrediting organization. Accrediting organizations for ASCs include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for the Accreditation of Ambulatory Surgery Facilities (AAAASF) and the American Osteopathic Association (AOA). ASCs must meet specific standards during on-site inspections by these organizations in order to be accredited. All accrediting organizations require an ASC to engage in external benchmarking, which allows the facility to compare its performance to the performance of other ASCs.

Finally, ASCs that are not licensed by DPH and are not Medicare-certified are not subject to any of these requirements, although they might follow the Massachusetts Medical Society's Office Based Surgery Guidelines (but are not required to do so).

2. What are the current quality and safety reporting requirements for these facilities? What are differences between them?

ASCs must undergo an evaluation of quality standards in accordance with federal law.[18] They must engage in an ongoing assessment of the quality of care they provide, as well as the medical necessity of procedures. However, for unlicensed ASCs there is no state or federal process for ensuring that the clinic is meeting these standards.

Massachusetts requires that all complications and pre/post-operation services and procedures be reviewed internally by staff and the clinic. Licensed centers are required to report incidents occurring on the premises which seriously affect the health and safety of patients.[19] However, unlicensed and Medicare-certified only ASCs are not required to report such incidents to either CMS or DPH.

[18] CFR 426.43
[19] 105 CMR 140.307

A hospital-affiliated ASC operated under the hospital's license must adhere to conditions of that licensure, including, but not limited to:

- participating in the Board of Registration in Medicine risk management program set out in M.G.L. c. 111, §203(d) and 243 CMR 3.00, *et seq;*
- granting DPH the right to inspect, unannounced, the facility, staff, activities and records;
- submitting a plan of corrections in response to DPH statement of deficiencies found on inspection;
- establishing serious complaint procedure and reporting to DPH.

A clinic-type ASC operated under a clinic license must adhere to licensure conditions including, but not limited to:

- participating in a limited Qualified Patient Care Assessment Program;
- granting DPH the right to inspect, unannounced, the facility, staff, activities and records;
- submitting a plan of corrections in response to DPH statement of deficiencies found on inspection;
- establishing a serious complaint procedure and reporting to DPH;
- adhering to the staffing and procedure requirements for clinics providing surgical services set out in 105 CMR 140.600 subpart F.

Physician-owned ASCs have no similar requirements, although the Board of Registration in Medicine encourages, but does not require, its licensees to follow the Massachusetts Medical Society's Office Based Surgery Guidelines.

3. What is the state of current research concerning quality, safety and medical error rates at ASCs vs. hospitals, and what differences (if any) does it show?

Some research indicates that there are no significant differences in quality between ASCs and hospitals. A 1993 study from the University of Toronto examined the overall and complication related readmission rates within 30 days of surgery at an ASC. Very low readmission rates were observed, with only 1.1 % of the patients readmitted, and only .15% as a direct result of surgical complications. It is important to note, however, that the study does not provide any detail on the patient mix or the care provided to medically complex or low income patients. Unfortunately, due to the lack of reporting for any adverse incidents, utilization or discharge data, the Commonwealth cannot get a full

accounting of the quality, safety, and medical error rates associated with surgery performed in entities operating under the physician office exemption.

More recently, a 2004 study suggests that Medicare beneficiaries treated in freestanding ASCs fare as well as those who undergo surgery at hospitals. The authors analyzed claims data of 564,267 Medicare beneficiaries, of which 175,288 were treated at ASC's. The remaining patients were treated in office surgical and outpatient hospital settings. Ultimately, the study found that adverse events for patients in the ASC setting were among the lowest of all three sites of care, even after controlling for factors associated with higher patient risk. However, the authors noted that during the study period they "observed an increased risk-adjusted rate of inpatient hospital admission or death within 7 days of surgery for procedures initially performed in a physician's office compared with an outpatient hospital, suggesting the need for continued surveillance." It is important to note that the authors of this study specifically indicated that results are limited to the Medicare population and cannot be generalized to a younger population or procedures not covered by Medicare. As a result, there is no discussion of the low income populations that tend to include more medically complex patients. Further, the authors note one study limitation is that there is clear selection bias because certain types of patients are more appropriately treated in certain care locations.

4. What is the correct configuration of oversight, rules, etc. in regard to ASCs and hospitals?

In 2002 the Office of the Inspector General of the U.S. Department of Health and Human Services issued a report entitled *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*.[20] The report found that Medicare's system of quality oversight is not up to the task, and lacks accountability. It recommended that CMS determine an appropriate minimum cycle for surveying ASCs certified by state agencies. It also stated that the Medicare Conditions of Participation for ASCs should be updated to address patient rights and continuous quality improvement. The Inspector General stressed that

[20] Janet Rehnquist, Inspector General, *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*, OEI-01-00-00450 (Feb. 2002).

state agency certification must strike an appropriate balance between compliance and continuous quality improvement, rather than focusing exclusively on one or the other. The Federal Department of Health and Human Services has responded by launching a "Quality Initiative" under which members of the ASC industry, along with associations and related organizations with a focus on health care quality and safety, are working to identify specific measures for quality appropriate to ASCs.

5. How does the growth of ASCs affect utilization rates?

According to a March 2003 Medicare Payment Advisory Commission (MedPAC) report to Congress, the number of Medicare certified ASCs has more than doubled between 1991 and 2001. The volume of procedures provided to beneficiaries at ASCs increased by 60% between 1997 and 2001. Medicare payments to ASCs, including program spending and beneficiary cost sharing, increased by almost 17% in 2002 and more than tripled between 1992 and 2002.

MedPAC offers a number of reasons for the rapid increase in ASC spending. ASCs may offer patients more convenient locations, the ability to schedule surgery more quickly, and shorter waiting times than hospital outpatient departments. Medicare beneficiaries' coinsurance is generally lower in ASCs than in outpatient departments. Physicians may be able to perform surgeries more efficiently in ASCs because they often have customized surgical environments and specialized staffing. Changes in clinical practice and health care technology have expanded the provision of surgical procedures in ambulatory settings. Additionally, Medicare began covering colonoscopies for colorectal cancer screening in 1998. Finally, physicians who invest in ASCs can increase their practice revenue by receiving ASC facility payments. The federal anti-referral law does not apply to surgery services provided in ASCs, making it possible for physicians to own and provide care in these facilities.

MRI Questions and Discussion:

1. **What are the current safety requirements concerning imaging and diagnostic services?**

According to a presentation to the Commission by Gail Palmeri of the DPH Department of Healthcare Quality, MRIs located in licensed facilities are subject to compliance with American Institute of Architects Guidelines for Construction through an architectural plan review and approval for MRI. There are no specific state licensing/registration and only voluntary accreditation. Centers should conduct equipment monitoring in accordance with Manufacturer's Guidelines and staff training by general standards of practice.

2. **What reliable evidence is there concerning trends in utilization of imaging and other diagnostic services in Massachusetts?**

A growing body of national level data indicates that the volume of services being provided to consumers is increasing sharply. Testimony to the House Ways and Means Committee in 2005 from the executive director of MedPAC, Mark Miller, indicated that during the period between 1999 and 2003, the volume and complexity of imaging services grew by 45%. This is a rate that is double the growth of all other physicians' services (22%). Miller also pointed out that there are more MRI scanners in the Pittsburgh area than in all of Canada. In 2003, there were over 13 CT scans provided for every 100 members of the largest health plan in that area.

Medicare spending on these services grew over 60% from 1999 to 2003. According to the 2006 New England Journal Health Policy Report, insurers are continuing to ask whether this rise in use/spending of imaging services is directly related to improved patient outcomes. The author opines that the rapid growth in utilization of these services has been driven by medical technology advancements, but also by "physicians who have an interest in supplementing their professional fee with revenues from ancillary services."

A recent study using billing data from a large California insurer showed that in 2004 self-referring physicians accounted for 33% of MRIs, 22% of CT scans, and 17% of PET scans.[21] No similar data exist for imaging performed in Massachusetts. Studies consistently show that physicians who are not radiologists operating their own imaging equipment with the opportunity for self-referral have substantially higher utilization than physicians who refer patients to radiologists.[22]

3. What types of physician self-referral prohibitions/notifications are appropriate to guard against potential abuse in Massachusetts?

The federal Stark law generally prohibits physicians from referring Medicare patients to imaging facilities in which they hold an ownership stake. However, the law provides for a number of exceptions. Physicians who are hospital-based employees or members of a non-profit group practice are not subject to the Stark prohibitions.

The In-Office Ancillary Services Exception allows for self-referral if the service is provided as part of the physician's practice. This loophole can potentially be exploited through business models in which doctors ostensibly lease the equipment and employees of an imaging center at the time of service, thus holding no technical ownership in the practice. There is evidence of such leasing arrangements in Massachusetts.

The federal anti-kickback statute[23] makes it illegal for doctors to accept bribes or other compensation in return for generating Medicare, Medicaid or other federal healthcare program business. Also, a physician cannot offer anything of value to induce federal healthcare program business. The statute includes more than 20 permitted "safe harbors", such as investments in group practices.

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[21] Jean M. Mitchell, *The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging*, Health Affairs 26, no. 3 (2007): w415–w424.
[22] David C. Levin, Vijay M. Rao, *Turf Wars in radiology: The Overutilization of Imaging Resulting from Self-Referral*, J Am Coll Radiol 2004;1:169-172.
[23] 42 USC 1320a-7b.

4. What is the current status of physician exemption letters?

The Physician Letter of Exemption was intended to safeguard physician-owned and controlled acquisitions from the DoN process if the acquisitions were made or a notice of intent were filed by a specific date. While the letters did not include an expiration date, their transitional nature is evidenced by the fact that the "grandfathering" provisions of the amendments were never codified in law. Grandfather clauses are used only to apply to existing situations, and to ease the transition of eventually applying to all future situations. However, a lack of regulation of these exemption letters has enabled their use as freely transferable personal exemptions. Individuals have purchased these letters for prices upwards of $300,000. This includes some who have come in from out of state many years after the deadline to file a notice of intent. In 2001, legislation was passed prohibiting further use of physician exemption letters in Berkshire County.[24]

According to Joan Gorga, director of the Determination of Need Program at DPH, the department issued 24 exemption letters for MRIs, 14 letters for radiation therapy, and 16 letters for Positron Emission Tomography (PET). It is unclear exactly how many letters are currently in use, and in what capacity.

5. Should diagnostic MRI and CT services be subject to Federal or state regulatory oversight?

While the Stark law and anti-kickback statute do not apply to patients with private health insurance, private payers employ extensive utilization review procedures to ensure that ordered tests are medically necessary.[25] Despite this market safeguard, 36 states have passed additional anti-self-referral laws that apply Stark-like regulation to patients with private insurance. The Commission received no testimony from the private insurance industry regarding a perceived need for additional measures.

[24] Chapter 203 of the Acts of 2001, §18.
[25] Krasner, Jeffrey, "Blue Cross to require preapproval for scans", *Boston Globe*, Sept. 6, 2005

Phase III of the Stark regulations were expected in March 2007. It was anticipated that the law would be changed to address improper lease arrangements and other potential loopholes. However, CMS sought a delay and the timeline for publication was pushed back until March 26, 2008.

At the Commission hearing, Thomas S. Crane, an attorney with Mintz, Levni, Cohn, Ferris, Glovsky & Popeo, P.C., suggested that the Legislature wait to see what was in the new regulations before acting on the self-referral issue. He also suggested the possibility of applying the Stark and anti-kickback provisions to all payers in Massachusetts.

VI. Recommendations

At this time the Commission makes the following recommendations:

Ambulatory Surgical Centers:

1. Medicaid/Free Care Reimbursement

Ambulatory Surgical Centers (ASCs) that are certified by Medicare should be eligible for Medicaid and the Health Safety Net Care Fund (i.e., Uncompensated Care Pool) reimbursement, provided that potential cost-savings from such a change can be demonstrated. The goal of expanded eligibility should be achieved by creating a special accreditation process for the purpose of Medicaid and Health Safety Net Care Fund reimbursements with oversight and transparency requirements, to be overseen by the Office of Medicaid in consultation with the Department of Public Health (DPH). The current assessment paid by hospitals to the Uncompensated Care Pool and the successor Health Safety Net Fund should extended in an equitable fashion to ASCs that receive such reimbursement (with a corresponding decrease in assessments on hospitals). The Office of Medicaid and the Division of Health Care Finance and Policy should take steps to ensure that ASCs that are eligible for Medicaid and Health Safety Net reimbursements do not limit access to patients whose care is reimbursable from these sources.

2. DoN Process & Licensure

The state should revisit statutory definitions related to clinics and the physician office exemption and consider creating a separate definition and set of regulations for ASCs, including those currently operating under the physician office exemption. In addition, the Commission recommends that ASCs wishing to become specialty hospitals be required to go through the full DoN process.

3. Safety & Transparency

All ASCs should have a written agreement with an acute care hospital concerning emergency situations. The DPH should promulgate regulations setting reporting requirements that are consistent for hospitals and ASCs (both licensed and Medicare-

certified). Such reporting requirements should be consistent across facilities for each service or procedure subject to reporting. The Quality and Cost Council should have access to data reported under these requirements. In addition, the Commission recommends that DPH monitor the numbers and types of ambulatory surgical services performed at hospitals and freestanding ASCs, in order to analyze any potential detrimental impact on hospital finances. Such data should include the location of ASCs and a breakdown of types of cases treated and types of payers (Medicaid, Medicare, private, HMOs, Health Safety Net Fund), along with information concerning ownership.

4. Additional Concerns

While it was not a primary focus of the Commission's deliberations, some members expressed serious concerns about cases of existing hospitals expanding ambulatory and other services under their current license in to new geographic areas, particularly those areas where other hospitals currently exist. We believe this issue merits further attention.

Medical Diagnostic Technology

1. Registration and Sunset of Physician Letters of Exemption

DPH should establish a registry of physician letters of exemption in order to determine who currently owns the 54 letters that were issued, and whether each letter has been implemented. All letters should be registered with DPH by January 1, 2008. The registry should include the current owner of the letter, as well as the status of the project and its location. After that time all unregistered letters should be considered null and void. Once registered, letters should be considered non-transferable.

Registered exemption letters should be implemented by January 1, 2009, at which time the rights conferred by unimplemented letters will sunset. Registered letter holders should be able to appeal for an extension with the Public Health Council until July 1, 2009. Registered physician letters of exemption that are not in use as of January 1, 2008 should be subject to a DoN with an expedited review process to be set up by DPH, at

which time section 18 of Chapter 203 of the Acts of 2001 should be repealed. Letters in use before that date should be grandfathered in with no DoN required.

2. MRI Technology, Maintenance and Staff Requirements

Medical diagnostic equipment should be required to meet current technology standards and maintenance requirements. DPH should draft regulations that will provide for the credentialing of those who calibrate and maintain such equipment. The Board of Registration in Medicine should draft regulations that will provide for the credentialing for those who read and interpret such results. In addition, MGL 111, §5Q(b), which currently regulates mammography facilities, should be amended to apply to all imaging technology, including but not limited to MRI, CT and PET.

3. Piggybacking Stark and Anti-Kickback in state law

The legislature should act to address potential self-referral issues with respect to state payers (MassHealth, Commonwealth Care, and the Group Insurance Commission). The best way to accomplish this is to piggyback the provisions of both the Stark law and the anti-kickback statute, including all exceptions and safe harbors, in state law. The attorney general should be charged with enforcement of these provisions.

This will allow the state provisions to stay flexible, and will not require frequent amendments as these laws are changed at the federal level. However, with CMS delaying the publication of its new regulations on the subject, the Commission feels that the potential problem of improper leasing arrangements should be immediately addressed by the state. Therefore, the legislature should apply all self-referral preclusions to physician leased, as well as physician owned facilities.

4. Licensing of Health Screening Providers

Legislation should be passed to require that anyone advertising or offering so-called preventative health screenings using ultrasound technology be licensed by the Commonwealth as a physician, nurse, or allied health professional. Those who operate and calibrate ultrasound equipment should be certified by either Cardiovascular Credentialing International, or the American Registry of Diagnostic Medical

Sonographers. Results should only be interpreted by a person who is board certified by the American Board of Radiology or the American College of Cardiology. These providers should be subject to further oversight by DPH and the Board of Registration in Medicine.

APPENDIX A

Stark Law Information session

1) "Stark Law Historical Perspective and Special Considerations" (presentation by Thomas Crane, Mintz Levin)
2) "General Court's Commission on Ambulatory Surgical Centers and Medical Diagnostic Services" (presentation by Dr. David Levin, Department of Radiology, Jefferson Medical College and Thomas Jefferson University Hospital)
3) Presentation by Wes Cleveland, American Medical Association

APPENDIX B

Determination of Need Information Session

1) "The Determination of Need Program" (presentation by Paul Dreyer, Bureau of Quality Assurance and Control, Massachusetts Department of Public Health)

APPENDIX C

Public Hearing Testimony

1) Agenda
2) List of witnesses (as signed in)
3) Invited testimony
   - Thomas Crane
   - Jean Mitchell
   - John Blair
   - Joan Gorga
   - Gail Palmeri
   - David Shapiro
4) Other written testimony
   - Mark Taylor, CEO, New England PET Imaging System/Merrimack Valley MRI
   - Carol A. Straney, Area Center manager, MRI of Dedham
   - Jeffery Levin-Scherz, MD, CMO, Atrius Health
   - Darlene Marini, Vice President, Massachusetts Association of Ambulatory Surgery Centers
   - Massachusetts Hospital Association
   - Andrew Whitman, Vice President, Medical Imaging and Technology Alliance
   - Peggi Keegan, BSN, RN
   - Kreg Palko, East Bay Surgery Center
   - Hoagland Rosania, MD
   - Theodore A. Calianos II MD FACS
   - Richard M. Bargar, MD
   - Peter E. Bentivegna, MD FACS
   - George Picard, Greater New Bedford Surgicenter
   - Dr. George Violin, MD
   - Dr. Kevin Mitts, Berkshire Orthopaedic Associates
5) Other Submissions
   - Accreditation Association for Ambulatory Health Care, Inc., Physical Environment Checklist
   - Accreditation Association for Ambulatory Health Care, Inc., Accreditation Handbook 2005
   - JACHO Comprehensive Accreditation Manual for Ambulatory Care 2005-2006
   - Massachusetts Medical Society, Physician Workforce Study, June 2006
   - Jean M. Mitchell, *The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging*
   - *People of the State of Illinois vs. Midi LLC, et al*, Complaint
   - Siemens Medical, *Imaging Opportunities for ENT Physician Practices*

APPENDIX D

D. Additional Comment from Commission Members

1) Massachusetts Hospital Association
2) Massachusetts Medical Society
3) Massachusetts Association of Ambulatory Surgery Centers
4) Fallon Clinic